APR 1 6 2010

K093780

Attachment #1

VII. SECTION 10 - 510(K) SUMMARY

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date of Summary preparation: December 9, 2009

1. **Applicant's Name and Address**

Astra Tech Inc.

590 Lincoln Street

Waltham, Massachusetts 02451

Telephone Number: 781-810-6462

Fax Number: 781-810-6719

Contact Person: Franklin Uyleman

Manager of Quality and Regulatory Affairs

2. **Name of Device**

Trade Name: Atlantis™ Abutment for Dentsply Implant

Common Name: Endosseous dental implant abutment

Classification Name: Endosseous dental implant abutment

21 CFR 872.3630 Product code NHA

3. **Legally Marketed Device to which Equivalence is claimed (Predicate Device)**

Manufacturer	Device	510(k) Number
Dentsply International, Inc.	Frialit Plus, XIVE ® S Plus Dental Implant System	K073075
Atlantis Components Inc. (currently Astra Tech)	Atlantis Abutment in Zirconia	K052070

4. **Description of the Device**

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented or screw retained restorations. The **Atlantis™ Abutment for Dentsply Implant** and **abutment screw** are made from Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136) for the 3.0mm, 3.4mm, 3.8mm, 4.5mm, 5.5mm and 6.5mm sizes. In addition, the **Atlantis™ Abutment for Dentsply Implant** for the 3.4mm, 3.8mm, 4.5mm, 5.5mm and 6.5mm sizes, also are made of the biocompatible material, yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) (meets ISO Standards 6072 & 13356). Zirconia may have a variation in shade. The titanium and the zirconium abutments are placed over the implant shoulder and are mounted into the implant with a titanium screw.

5. **Intended Use of the Device**

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

5. Intended Use of Device (continued):

This device is compatible with the following manufacturers' implant systems:

The titanium abutments are compatible with the Dentsply 3.0mm, 3.4mm, 3.8mm, 4.5mm and 5.5mm XiVE® S Plus Implants.

The titanium and zirconia abutments are compatible with the Dentsply 3.4mm, 3.8mm, 4.5mm, 5.5mm and 6.5mm Frialit® Plus Implants.

The zirconia abutments are compatible with Dentsply 3.4mm, 3.8mm, 4.5mm and 5.5mm XiVE® S Plus Implants.

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.

6. Basis for Substantial Equivalence

The **Atlantis™ Abutments for Dentsply Implants** are substantially equivalent in intended use, material, design and performance to the Dentsply Frialit Plus, XIVE S Plus Dental Implant System cleared under K073075 and the Atlantis Components Inc. (currently, Astra Tech) Zirconia Abutment cleared under K052070.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 1 6 2010

Astra Tech, Incorporated
C/O Ms. Betsy A Brown
Consultant
B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60076

Re: K093780
Trade/Device Name: Atlantis™ Abutment for Dentsply Implant
Regulation Number: 21CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 29, 2010
Received: March 30, 2010

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known) K093780

Device Name: Atlantis ™ Abutment for Dentsply Implant

Indication for Use:

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

This device is compatible with the following manufacturers' implant systems:

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The titanium and zirconia abutments are compatible with the Dentsply 3.4mm, 3.8mm, 4.5mm, 5.5mm and 6.5mm Frialit® Plus Implants.

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Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.
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Prescription Use X (Part 21 CFR 801 SubpartD) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ASBetz DDS for Dr. K.P. Mulry
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093780